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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,579	09/17/2003	Henry Kahle	A-2845-AL	9166
21378	7590	03/14/2006	EXAMINER	
APPLIED MEDICAL RESOURCES CORPORATION			DOE, GRACE SC	
22872 Avenida Empresa			ART UNIT	
Rancho Santa Margarita, CA 92688			PAPER NUMBER	
			3732	
DATE MAILED: 03/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/666,579	Applicant(s) KAHLE ET AL.	
	Examiner Grace SC Doe	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005 and 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's provisional election of claims 1-16 and 25-35 in the reply filed on 12/8/05 is acknowledged. Due to unity of invention in Applicant's corresponding PCT application, all the claims 1-35 have been examined.

Information Disclosure Statement

2. The references cited in the Search Report are acknowledged and in compliance with 37 CFR 1.97 and 1.98.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "up to about" in claims 1 and 25 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. With regards to claims 8 and 18, the use of the word "inserted" is

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unclear. Claims 17-24 recite a "valve" and "valve structure" limitations. There is insufficient antecedent basis for this limitation in the claim. With regards to claims 17-19, it is unclear as to which valve the term "the valve structure" is referring.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Loomas (US 5,407,433). Loomas discloses a surgical access device including a valve structure (See figure 1) and a valve within the valve structure (See figure 1, parts 84,86, and 88). The valve has a first state having a zero seal wherein no instrument is introduced (See col. 13, lines 14-17) and a second state wherein an instrument extends through and forms a seal with the valve (See col. 13, lines 17-22).

7. Claims 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Blake (US 5,865,807). Blake discloses a surgical access device including a valve structure (See figure 3) and a valve within the valve structure (See figure 3, part 36). The valve has a first state having a zero seal wherein no instrument is introduced (See col. 4, lines 55-56, 60-61) and a second state wherein an instrument extends through and forms a seal with the valve (See figure 6).

8. Claims 1-13 and 16-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Ewers (US Patent Publication 2004/0015185). Ewers discloses a surgical access device capable of receiving a surgical instrument of about 37 mm in diameter. The device includes a valve having an elastomeric gel, access channel, and sleeve (See figure 32, parts 35 and 147). The elastomeric gel may include a silicone, urethane, urethane foam gel, elastomeric oil mixture, and vegetable oil (See claims 2-7). The cap ring is molded with the gel (See col. 15, lines 45-47). The sleeve is molded around the inner diameter of a cap ring (See figure 32, part 147; col. 15, lines 45-50). The device includes a support ring and wound retractor having an inner ring, outer ring, and flexible sleeve (See figure 32, parts 152, 154, and 147). The sleeve can be a single tubular member (See figure 32, part 147). The protective sleeve and cap ring may be composed of different materials (See col. 8, lines 1-3, 42-46). Ewers further discloses a valve within a valve structure having a first and second state (See claim 12). As discussed above, the valve structure includes a cap ring molded with the valve, protective sleeve bonded to the cap ring, a support ring, and a wound retractor. Ewers further discloses a valve structure having an elongate configuration (See figure 32), valve wall (See figure 32, part), and working channel capable of accommodating a 37 mm instrument (See figure 32). Ewers further discloses an abdominal base (figure 32, part 145). The gel cap includes a gel pad (See figure 32, part 35s), cap ring (See figure 32, part 154), and a bonded sleeve (See figure 32, part 147). As discussed above, Ewers in view of Hart discloses a sleeve having a plurality of sleeve members and slits.

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The cap ring has an annular void (See col. 9, line 55). The base has a rounded end surface (See figure 32), raised wall (See figure 36), and a plurality of toggles, latches, and mating features (See figure 36, part 156).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-3, 5-8, 10-12, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomas (US 5,407,433) in view of Hillstead (US 4,895,565). Loomas, discussed above, discloses a surgical access device. The access device has a valve structure (See figure 1), access channel (See figure 1, part 38), and protective sleeve (See figure 1, parts 12 and 14). The device is capable of receiving a surgical instrument of large diameters (See col. 9, lines 20-27, 31-34, 37-49; col. 10, lines 1-3). Although

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Loomas fails to explicitly mention the ability to accommodate an instrument about 37 mm in diameter, Loomas does disclose the ability to insert large diameter instruments (See col. 9, lines 37-49, 68; col. 10, lines 1-3) and teaches the ability to accommodate instruments of varying diameters by changing the diameter of the instrument port (See col. 9, lines 31-34). Loomas also fails to disclose an elastomeric gel. Hillstead teaches an elastomeric gel (See col. 4, lines 54-60) including a silicone (See col. 3, lines 13-20) or a urethane (See col. 4, lines 54-55). The elastomer includes a base and oil, such as silicone, creating an elastomeric oil mixture (See col. 3, lines 20-27). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Loomas by incorporating Hillstead's silicone, urethane, or silicone oils in order to achieve greater lubrication and customize performance parameters of the seal (See col. 3, lines 25-27; col. 4, lines 56-57). Loomas further discloses a cap ring (figures 1 and 3A, part 66; col. 10, lines 62-63), but fails disclose the ring molded with the gel. Loomas does disclose the ring attached to the gel sealing structure (See col. 11, lines 67-68; col. 12, lines 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to mold the cap ring to the gel, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893). The device includes a sleeve capable of providing for wound protection (See figure 1, parts 12 and 14). The language of claim 10 regarding wound protection is functional language directed to intended use and therefore has little patentable. Loomas further discloses a support ring located around

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the circumference of the valve (See figure 3A, part 42) forming a hollow wherein a wound retractor is located (See figure 3A, part 52; col. 10, lines 30-45). The wound retractor includes an inner ring (See figure 3B, part 50), outer ring (See figure 3B, part 42), and a interconnecting flexible sleeve (See figure 3B). As discussed above, Loomas in view of Hillstead discloses a valve structure and a gel capable of forming a seal with an instrument having a diameter about 37mm. Loomas also discloses a valve structure having a wall(See figure 2, part 26) and working channel (See figure 1, part 38). The device includes a gel cap (See figure 1, part 32) and abdominal base (See figure 1, part 60).

12. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomas (US 5,407,433), in view of Hillstead (US 4,895,565), and further in view of Taylor (US Pub. 2004/0106942). Loomas in view of Hillstead, discussed above, fails to disclose a foam gel. Taylor teaches an elastomer incorporating a urethane (See col. 4, lines 41-45). The device includes a foam gel composed of a foaming agent and urethane (See col. 4, lines 41-45). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify Loomas in view of Hillstead by incorporating the urethane foam of Taylor in order to obtain desirable mechanical and material properties.

13. Claims 9, 13-14, 27-31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers (US Patent Publication 2004/0015185) or Loomas (US

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5,407,433), in view of Hillstead (US 4,895,565), and further in view of Hart (US 5,803,919). Loomas in view of Hillstead, discussed above, fails to disclose a sleeve around the inner ring of the cap. Hart discloses a sleeve bonded around the inner diameter of the cap ring (See figure 2, parts 56 and 50; col. 4, lines 27-30). Hart also teaches a plurality of axially extending sleeve members (See figure 2, parts 61a-61d) having a plurality of slits (See figure 2, cuts or openings between parts 61a-61d) in order provide an improved zero closure mechanism that accounts for the fluid pressure within the incision area and reduce friction forces when inserting an instrument (See col. 4, lines 32-36). Therefore it would be obvious to one of ordinary skill in the art to modify the device of Ewers or Loomas in view of Hillstead with the sleeve of Hart in order to reduce frictional forces and improve the zero seal mechanism (See col. 4, lines 32-36). Loomas further discloses that the protective sleeve is a singular tubular member (See figure 1, parts 12 and 14). Loomas in view of Hillstead and Hart, discussed above, discloses a gel cap including a gel pad (See figure 1, part 32), cap ring (See figure 1, part 44), and sleeve bonded around an inner diameter of the cap ring. Loomas further discloses that the cap ring has an annular void located on its inner circumference capable of forming a sealing relationship with the base (See figure 3B, instep between parts 50 and 32). The base has a rounded end surface along its inner diameter capable of securing a wound retractor (See figure 3B, part 72). The base also includes a raised wall along its inner diameter (See figure 3B, part 72) capable of fitting a cap ring.

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14. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers (US Patent Publication 2004/0015185) or Loomas (US 5,407,433), in view of Hillstead (US 4,895,565), in view of Hart (US 5,803,919), and further in view of Boretos (US 4,222,126). Loomas in view of Hillstead and Hart fail to explicitly disclose the material of the cap ring and sleeve. Boretos discloses a cap ring (See figure 1, part 12) and sleeve (See figure 1, parts 14a-14c) that may be made of the same (See col. 6, lines 4-7) or different (See 8-11) material in order to achieve desirable material properties such as biocompatibility and strength (See col. 6, lines 8-12). Boretos is considered to be analogous art because the disclosed material is reasonably pertinent to the particular problem with which Applicant is concerned, selecting a desirable material for use in fabricating the surgical access device. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ewers or Loomas in view of Hillstead and Hart with Boretos' material selection in order to design a biocompatible device. Further, it would be an obvious matter of choice to one of ordinary skill in the art compose the sleeve and cap ring from the same or differing materials depending upon desirable mechanical properties and economic and manufacturing constraints.

15. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomas (US 5,407,433), in view of Hillstead (US 4,895,565), in view of Hart (US 5,803,919), and further in view of Antoon (US 5,628,732). Loomas in view of Hillstead and Hart fail to disclose a plurality of toggles or latches. Antoon discloses a plurality of

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latches, notches, and mating means (See figure 3). Therefore it would be obvious to one of ordinary skill in the art to modify the device of Loomas in view of Hillstead and Hart with the mating features of Antoon in order to secure together the various components of a surgical access seal.

16. Claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blake (US 5,865,807) in view of Hart (US 5,803,919). Blake, discussed above, discloses a cap ring (figure 3, part 2) but fails to teach the cap ring molded with the valve structure. Hart discloses a cap ring molded to the valve structure (See col. 4, lines 23-32) and a sleeve bonded around the inner diameter of the cap ring (See figure 2, parts 56 and 50; col. 4, lines 27-30). Hart also teaches a plurality of axially extending sleeve members (See figure 2, parts 61a-61d) having a plurality of slits (See figure 2, cuts or openings between parts 61a-61d) in order provide an improved zero closure mechanism that accounts for the fluid pressure within the incision area and reduce friction forces when inserting an instrument (See col. 4, lines 32-36). Therefore it would be obvious to one of ordinary skill in the art to modify the device of Blake with the sleeve of Hart in order to reduce frictional forces and improve the zero seal mechanism (See col. 4, lines 32-36). Blake further teaches a support ring circumferentially located around the valve (See figure 3, part 36a) and a wound retractor located within (figure 3, part 36). The wound retractor includes an inner ring (See figure 3, part 36a), outer ring (See figure 3, part 36b), and flexible sleeve (See col. 4, lines 48-50). Blake also discloses a single tubular sleeve, which provides for wound protection (See figure 3, part 38).

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No.

10/381,220 in view of Blake (US 5,865,807) and Antoon (US 5,628,732). Although the conflicting claims are not identical, they are not patentably distinct from each other because as to claims 1 and 25, '220 discloses in claim 1 and 20 a valve structure including a gel, elastomer, and access channel. '220 fails to explicitly disclose a sleeve and a channel capable of accommodating an instrument 37 mm in diameter. Blake discloses a sleeve (See col. 5, lines 10-13). Therefore it would be obvious to one of

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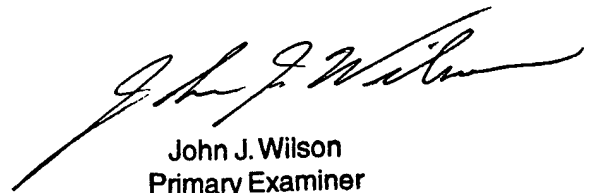
ordinary skill in the art at the time of the invention to modify Ewers in view of Blake in order to act as an instrument guide (See col. 5, lines 10-13). Ewers in view of Blake fails to explicitly disclose accommodating an instrument of 37 mm in diameter. It would be an obvious matter of choice to one of ordinary skill in the art to design the valve to accommodate instruments 37 mm in diameter in order to enable surgeons to utilize larger or multiple instruments. With regards to claims 8-9, 18-19, and 26-27 it is an obvious matter of choice to one of ordinary skill in the art to arrange the location and relative orientation of the components of a valve structure. With regards to claims 10-12 and 21-22, Blake discloses a wound retractor as a means of creating an additional seal in the surgical access valve. With regards to claims 13-16, 20-24, and 28-29 it is an obvious matter of choice to one of ordinary skill in the art to arrange the features and material composition of the sleeve so as to enhance the zero seal and ability to guide inserted instruments. With regards to claim 17, '220 discloses the limitations of claim 7 in claim 12. With regards to claims 31-35, Ewers in view of Antoon (US 5,628,732) discloses a number of mating features between the base and cap ring. Therefore it would be obvious to one of ordinary skill in the art to modify Ewers with Antoon in order to secure together the components of the valve structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Grace SC Doe whose telephone number is (571) 272-2831. The examiner can normally be reached on 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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